

# **EXHIBIT B**



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

12/21/2016

NEW YORK UNIVERSITY  
CHARLES SEIFE  
20 COOPER SQUARE 6TH FL  
NEW YORK NY 10003 USA

In Reply refer to:  
2016-10322  
Requester Control #:

Dear Requester:

This is in reference to your request(s) for record(s) from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act (FOIA).

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The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."

I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing. The responding agency office will process your request in the order in which it was received.

You have the right to appeal this determination. Your appeal must be mailed within 90 days from the date of this response, to: Ms. Catherine Teti, Deputy Agency Chief FOIA Officer, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Public Affairs, Room 729H, 200 Independence Avenue, S.W., Washington, DC 20201. Please clearly mark both the envelope and your letter "Freedom of Information Act Appeal." If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact this office at: DFOI, 5600 Fishers Lane, Room 1035, Rockville, MD 20857, 301-796-3900, FDAFOIA@fda.hhs.gov.

You may also contact the HHS FOIA Public Liaison for assistance at: Michael Bell, HHS FOIA Public Liaison, U.S. Department of Health and Human Services  
Office of the Assistant Secretary for Public Affairs, Room 729H, 200 Independence Avenue, S.W., Washington, DC 20201, Telephone: (202) 260-0793, E-mail: HHS\_FOIA\_Public\_Liaison@hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies.

The contact information for OGIS is: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road—OGIS, College Park, MD 20740-6001, Telephone: 202-741-5770, Toll-Free: 1-877-684-6448, E-mail: [ogis@nara.gov](mailto:ogis@nara.gov), Fax: 202-741-5769.

Sincerely Yours,

SARAH KOTLER  
Director